



Idaho Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Compliance Officer

Lisa Culley, Idaho Board of Pharmacy compliance officer for southern Idaho since 2000, has resigned as of July 14, 2006. Lisa has been an excellent compliance officer and will be missed not only by the Board and staff but by her many friends throughout the area. The Board is in the process of hiring another compliance officer at this time.

Controlled Substance Prescriptions

After much discussion between the Idaho Board of Pharmacy and the Idaho Pharmacists Association, the following changes were made to Rule 464 concerning the filling of controlled substance (CS) prescriptions. The changes deal primarily with positive identification and maintaining records of patients for future identification. This is a temporary rule with an effective date of July 31, 2006. The Board will pursue making the rule permanent during the 2007 legislative session. The following is a copy of the rule in its entirety. The Board suggests that you place this *Newsletter* in your Law Book for future reference.

464. Filling of a Prescription for a Controlled Substance

01. Filling and Dispensing. No person other than a registered pharmacist under the laws of this state shall be responsible for the filling and dispensing of a prescription for a [CS].

02. Identification. Persons receiving [CS] shall be positively identified by staff at the pharmacy at the time any [CS] is dispensed directly to an individual at the pharmacy.

- a. Positive identification shall consist of either a valid, current state or military drivers license or identification card, or a valid, current passport, each of which must contain a photo of the individual and the individual's signature. For each [CS] prescription dispensed directly to an individual at the pharmacy, the pharmacy shall maintain a record of:
 - i. The name of the person receiving the prescribed [CS] (if other than the patient);
 - ii. The type of positive identification presented by such person;
 - iii. The state, military branch or other governmental entity issuing the identification; and
 - iv. The specific identification number of the drivers license, identification card or passport.
- b. In lieu of these means of positive identification, an individual whose identity is personally and positively

known to a staff member of the pharmacy who is present and who identifies the individual at the time of delivery of the prescribed [CS] may be so identified by the staff member; in such instances, the pharmacy shall maintain a record of;

- i. The name of the person receiving the prescribed [CS] (if other than the patient);
- ii. A notation indicating that the patient or other person receiving the prescribed [CS] was known to the pharmacy staff; and
- iii. The name of the pharmacy staff person making the identification.

03. Retrieval of identification records. The identification records required under Subsection 464.02 of this rule may be maintained by the pharmacy in any fashion provided that the pharmacy must be able to produce such records upon any lawful request, and match the prescription filled with the positive identification records for the person receiving the prescribed [CS], within no more than two (2) business days from the date of the request.

Albuterol Prescriptions

The following letter has been sent to practitioners in Idaho concerning prescriptions written for albuterol.

Dear Idaho Prescriber,

On December 31, 2008, [Food and Drug Administration] will no longer allow any prescriptions for albuterol to contain its current propellant – [c]hlorofluorocarbon (CFC), and all such canisters of albuterol or like medications must use [h]ydrofluoroalkane (HFA). In the interim, there have been shortages of albuterol canisters as manufacturers convert to the HFA propellant. With the associated increased cost of HFA container materials challenging payor systems to define a reimbursement/payment strategy for this essential rescue/chronic medication, substitution of propellant vehicles has been limited by affordability, and also by variance in understanding of generic substitution issues.

In order to avoid lack of emergent or chronic access to CFC or HFA albuterol by a patient, and the associated increased morbidity and utilization of emergency departments,

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Generic Substitution Issues

This is a reminder to pharmacists regarding the legal generic substitution of certain drug products. Recent practices by pharmaceutical manufacturers involving the reformulation of drugs into alternative dosage forms (eg, tablets to capsules) seem to have caused some confusion.

Generic substitution is the act of dispensing a different brand or unbranded drug product than the one prescribed. Generic substitution is only allowable when the substituted product is therapeutically equivalent to the prescribed innovator product. Generic drug manufacturers must provide evidence to Food and Drug Administration (FDA) of therapeutic equivalence, which means that both products are pharmaceutically equivalent (eg, have the same active ingredients in the same dosage form and strength, and use the same route of administration) and bioequivalent (eg, have more or less the same rate and extent of absorption). Therapeutically equivalent drugs are expected to produce the same clinical benefits when administered for the conditions approved in the product labeling.

FDA assigns two-letter therapeutic equivalence codes to generic products when the products meet both the aforementioned requirements, are approved as safe and effective, are adequately labeled, and are manufactured in compliance with current Good Manufacturing Practice regulations. The primary reference guide for pharmacists on therapeutic equivalence is FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book." Drug products determined to be therapeutically equivalent to innovator drugs are assigned an "A" for the initial letter of their therapeutic equivalence code. The second letter provides additional information regarding the product: products rated AA, AN, AO, AP, or AT are those with no known or suspected bioequivalence problems (rating depends on dosage form). An AB rated product indicates that actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence. In contrast, drugs assigned a "B" for the initial letter are not considered therapeutically equivalent because bioequivalence problems have not been resolved to the satisfaction of FDA.

A recent example of improper substitution has been brought to the attention of several boards of pharmacy by Acorda Therapeutics, the maker of Zanaflex® tablets, who recently released Zanaflex Capsules™ (tizanidine hydrochloride). Although the active ingredient in Zanaflex Capsules is the same as the active ingredient in Zanaflex tablets and generic tizanidine tablets, their formulations are different. For this reason, FDA has deemed there to be no therapeutic equivalent to Zanaflex Capsules and has not assigned a therapeutic equivalence code.

A similar situation existed in 1995 when the manufacturer of Sandimmune® (cyclosporine) capsules and oral solution, Sandoz, (now Novartis), came out with NEORAL® (cyclosporine) capsules and oral solution for microemulsion. Due to differences in bioavailability, Sandimmune and Neoral, and their accompanying generic versions, were not, and still are not, rated as substitutable.

It must be emphasized that generic substitution mandates are found in individual state laws and regulations. In states where generic substitution is allowed only for "Orange Book" A-rated

products, pharmacists may not substitute a generic product for a non-A-rated product. Some states may have developed their own generic substitution lists or formularies. Pharmacists are encouraged to review the laws and regulations in their states to determine the appropriate legal methods by which to perform generic substitution.

Preventing Errors Linked to Name Confusion



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

The Institute for Safe Medication Practices (ISMP) regularly hears about confusion between products with similar names. One such pair is OMACOR (omega-3-acid ethyl esters) and AMICAR (aminocaproic acid) an antifibrinolytic. Omacor is indicated as an adjunct to diet to reduce very high triglyceride levels (500 mg/dL or more) in adult patients. The drug is also being studied as adjuvant therapy for the prevention of further heart attacks in patients who have survived at least one. A pharmacist reported an error in which a telephone order for Omacor 1 gram BID was interpreted and dispensed as Amicar 1 gram BID. Counseling was not provided, but fortunately the patient read the drug information sheet for Amicar before taking any medication and called the pharmacy stating that he was expecting a medication to reduce his triglyceride levels.

While this case illustrates why manufacturers should review and test new trademarks for error potential before the product reaches the market, there are some things that practitioners can do to help prevent errors with products that have look-alike or sound-alike names.

- ◆ Look for the possibility of name confusion before a product is used. Use the concepts of failure mode and effects analysis (FMEA) to assess the potential for error with new medications that will be prescribed or added to your inventory. If the potential for confusion with other products is identified, take the steps listed below to help avoid errors.
- ◆ Prescriptions should clearly specify the drug name, dosage form, strength, complete directions, as well as its indication. Most products with look- or sound-alike names are used for different purposes. If the indication is not available, pharmacists and nurses should verify the purpose of the medication with the patient, caregiver, or physician before it is dispensed or administered.
- ◆ Reduce the potential for confusion with name pairs known to be problematic by including both the brand and generic name on prescriptions, computer order entry screens, prescription labels, and MARs.

Compliance News

Compliance News to a particular state or jurisdiction should not be assumed to be the law of such state or jurisdiction.)



- ◆ When accepting verbal or telephone orders, require staff to write down the order and then perform a read back (or even spell back) of the medication name, strength, dose, and frequency of administration for verification.
- ◆ Change the appearance of look-alike product names on computer screens, pharmacy product labels, and MARs by emphasizing, through bold face, color, and/or tall man letters, the parts of the names that are different (eg, hydrOXYzine, hydrALAzine).
- ◆ Pharmacists should work under good lighting and use magnifying lenses and copyholders (keep prescriptions at eye level during transcription) to improve the likelihood of proper interpretation of look-alike product names.
- ◆ Install computerized reminders for the most commonly confused name pairs at your site so that an alert is generated when entering prescriptions for either drug. If possible, make the reminder auditory as well as visual.
- ◆ Store commonly confused products in different locations. Avoid storing both products in a "fast-mover area." Use a shelf sticker to help find relocated products.
- ◆ Affix "name alert" stickers to areas where look- or sound-alike products are stored (available from pharmacy label manufacturers) or to the actual product containers.
- ◆ Employ at least two independent checks in the dispensing process (one person interprets and enters the prescription into the computer and another compares the printed label with the original prescription as well as the manufacturer's product).
- ◆ Open the prescription bottle or package in front of the patient to confirm the expected appearance of the medication and review the indication. Caution patients about error potential when taking a product that has a look- or sound-alike counterpart. Encourage patients to ask questions if the appearance of their medication changes. Take time to fully investigate any patient concerns.
- ◆ Encourage reporting of errors and potentially hazardous conditions with look- and sound-alike names to the ISMP-USP Medication Errors Reporting Program and use the information to establish priorities, as listed above, for error reduction. Maintain an awareness of problematic product names and error prevention recommendations provided by ISMP (www.ismp.org), FDA (www.fda.gov), and USP (www.usp.org).

If you are interested in learning what look-alike and sound-alike name pairs have been published in the ISMP Medication Safety Alert!®, a free list is available at www.ismp.org/Tools/confuseddrugnames.pdf.

Combat Methamphetamine Epidemic Act Phasing In

This year, new requirements of the federal Combat Methamphetamine Epidemic Act passed by Congress for the sale of all single and multi-ingredient pseudoephedrine and ephedrine-containing products will become effective. The new law places non-prescription ephedrine, pseudoephedrine, and phenylpropanolamine in a new Controlled Substances Act category of "scheduled listed chemical products." Drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine are subject to sales restrictions, storage requirements, and record keeping requirements.

A 3.6-grams-per-day base product sales limit, 9-grams-per-30-days base product purchase limit, a blister package requirement, and mail-order restrictions went into effect on April 8, 2006,

for all sellers of these products. All other provisions of the law require compliance by September 30, 2006. If a state has more stringent requirements, the stronger requirements remain in place. A summary of this Act's requirements can be found on the United States Drug Enforcement Administration's (DEA) Web site at www.deadiversion.usdoj.gov/meth/cma2005.htm.

Explanation of DEA Regulations on Partial Refilling of Prescriptions

Pharmacists often question the DEA rule regarding the partial refilling of Schedule III, IV, and V prescriptions as stated in Section 1306.23 of the Code of Federal Regulations. Confusion lies in whether or not a partial fill or refill is considered one fill or refill, or if the prescription can be dispensed any number of times until the total quantity prescribed is met or six months has passed. According to DEA's interpretation, as long as the total quantity dispensed meets the total quantity prescribed with the refills and they are dispensed within the six-month period the number of times it is refilled is irrelevant. The DEA rule is printed below:

Section 1306.23 Partial Filling of Prescriptions.

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that:

- (a) Each partial filling is recorded in the same manner as a refilling,
- (b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and
- (c) No dispensing occurs after 6 months after the date on which the prescription was issued.

[21 CFR 1306.23]

Electronic Version of DEA Form 106 Now Available

DEA has announced that a secure, electronic version of the DEA Form 106 (Report of Theft or Loss of Controlled Substances) is now available to DEA registrants. The electronic form may now be completed online through a secure connection and submitted via the Internet to DEA Headquarters. Copies of the letter from DEA and the 2005 Final Rule were published in the *Federal Register*. The new interactive form is located at the Diversion Control Program's Web site and may be accessed at www.DEAdiversion.usdoj.gov.

Patients Rely on Pharmacists' Recommendations

Patients consider their pharmacists a trusted source for medication recommendations, as evidenced by the result of a poll recently conducted by the American Pharmacists Association (APhA). APhA polled 3,000 community pharmacists and found that pharmacists were asked about over-the-counter (OTC) products an average of 32 times each week. Of those pharmacists surveyed, 55% said they spend three to five minutes with each patient who asks about an OTC. And patients are listening, for during this consultation time, according to the survey, 81% of patients purchased OTC products recommended by the pharmacist.

The results of the poll was published in APhA's *Pharmacy Today*. Other topics researched in the poll include recommendation habits of pharmacists in leading OTC therapeutic areas including treatments for allergies, adult cold symptoms, adult headache remedies, heartburn, pain relief, and tooth whitening products among others.

and to assure greatest availability of the medication regardless of propellant source, as well as eliminate many call backs to prescribers by pharmacists for alternative authorization if out of stock, the Board of Pharmacy has authorized substitution of CFC and HFA as needed without contacting you.

In summary, when prescribing albuterol [metered dose inhalers] for your patients, substitution of CFC and HFA propellants is authorized by the pharmacist. However, substitution of albuterol and levalbuterol, because they are not equivalent drugs, will not occur without permission from the practitioner.

We are hopeful this will solve most issues that arise during this conversion period, and as payors make allowance for this substitution. Please contact any of the signatories if you have further questions.

Bob Seehusen, Idaho Medical Association

Jerry Hirschfeld, MD, American Academy of Pediatrics

Richard Schultz, Department of Medicaid

Peter Kozisek, MD, Idaho Association of Family Medicine

Steve Millard, Idaho Hospital Association

Richard Markuson, RPh, Idaho Board of Pharmacy

Controlled Substance Prescriptions

All CS prescriptions must include certain information as required by both state and federal law. This is true of both written and verbal prescriptions. Code of Federal Regulations 1306.05 states all prescriptions must have the patients full name, address, drug name, strength, dosage, quantity, and directions for use, as well as, the prescribers full name (not initials), address, phone number, and Drug Enforcement Administration number.

We have a number of practitioners with the same last name and first names beginning with the same initial, and without the above required information it becomes difficult during an investigation to determine who is the actual prescriber.

Idaho Code 37-2720, Records of Registrants, states that persons registered to manufacture, distribute, or dispense CS under this act shall keep records and maintain inventories in

conformance with the record keeping and inventory requirements of federal law and with any additional rules the Board issues.

Continuing Education

It is never too early to think about fulfilling your requirements for continuing education (CE). We try to post all of the CE programs being presented throughout the state on our Web site, www.state.id.us/bop. If your association or group is contemplating a program and needs Board approval, please try to send in the requests 30 days in advance. Make sure all attendees receive a certificate of attendance that includes the program date, content, presenter, and hours of credit; anything less will not be recognized as proof of CE. In review, a total of 15 clock hours of CE are required per year; a minimum of eight clock hours of Accreditation Council for Pharmacy Education (ACPE) or continuing medical education (CME), one hour of pharmacy law, a maximum of six hours may be a combination of non-ACPE and CME approved programs, and three hours must be obtained by attendance at live CE programs. Live programs cover all programs that provide for direct interaction between faculty and participants and may include lectures, symposia, live teleconferences, and workshops.

Special Notice

The Idaho Board of Pharmacy's *Newsletter* is considered one of the Board's official methods of notification to pharmacists and pharmacies. These *Newsletter* publications may be used in official Board actions as proof of notification. It is important to read the *Newsletters* carefully and to retain them as a future source of reference.

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